REGULATORY GUIDE B1

REGISTRATION OF FACILITIES AND X-RAY EQUIPMENT

South Carolina Department of Health
and Environmental Control

October 12, 2004

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REGULATORY GUIDE B1
REGISTRATION OF X-RAY FACILITIES AND EQUIPMENT

Each facility that has x-ray equipment must be registered with the Department. Registration of x-ray facilities and equipment is regulated under Regulation 61-64, X-Rays (Title B). Registration is a two-step process:

Step 1: Facility Registration Approval
Step 2: Equipment Registration

FACILITY REGISTRATION APPROVAL (see RHB 2.4)

Prior to installing an x-ray machine, a facility must apply to the Department for a Facility Registration Approval. The facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3. To receive a Facility Registration Approval, complete and return the back page of this guide along with the application fee, including the following information:

1) Facility Name, Location Address, and Mailing Address.
2) The name of the Radiation Safety Officer who is responsible for radiation protection, refer to RHB 1.6.4 .
3) Manufacturer, model #, and type of x-ray equipment to be installed. For example:
   Siemens Polydoros 80 Rad/Fluoro unit
   Belmont Model 071 Dental unit
4) Operating procedures as required by RHB 4.2.4, 6.3.2.1,7.8.3, or 8.8. (See Reg Guides B2, B3, B4, B7, B8, or B9 for assistance in writing operating procedures.)
5) A training plan as required by RHB 4.2.3, 7.8.1, or 8.11.
6) A shielding plan if required by RHB 4.4 or 8.13.2. (See Reg Guide B6)
7) FOR MOBILE FACILITIES ONLY, an operating schedule, indicating when and where the equipment will be used.
8) The name, address, registration number, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale and/or installation, then the above information must be provided for all companies involved.
9) Expected date of installation.

After receiving and reviewing the items above and all information is adequate, the Department will issue a Facility Registration Approval.

A FACILITY SHALL NOT INSTALL OR CAUSE TO BE INSTALLED AN X-RAY PRODUCING MACHINE UNTIL THE DEPARTMENT HAS ISSUED A FACILITY REGISTRATION APPROVAL.

For facilities registered with the Department prior to July 1, 1993, the facility registration approval will be required the first time new equipment is put in after July 1, 1993. For most facilities that routinely replace equipment, the information required in the facility registration approval process will only have to be submitted one time. Only information specific to the equipment being replaced would be required to be submitted. If a facility moves to a new location, a letter must be submitted to the Department stating the same procedures will be used, if a facility does not want to resubmit all of their procedures (unless procedure changes have been made). Facility Registration Approval is not transferable to a new owner or any additional locations.

EQUIPMENT REGISTRATION (see RHB 2.5)

When the Facility Registration Approval is issued, two equipment registration forms, DHEC form 819, will be sent to the facility. After the x-ray equipment is operational, the facility has thirty (30) days to return the completed equipment registration forms.

After receiving the equipment registration forms, the Department registers the controls and tubes, and issues an invoice for registration fees. Fees will be prorated for the remainder of the calendar year based upon the schedule of fees which is found in RHB 2.10. Registration fees must be paid within thirty (30) days.

Upon registration of a control, the Department shall issue the facility a registration sticker to be placed on each control. The registration sticker shall be placed on the control panel in a clearly visible location. When a control is removed from a facility, the facility shall remove the registration sticker. A registration sticker on a control, displaying the facility's proper name, shall be considered indicative of a facility's and a control's registration status, as required to be confirmed by RHB 2.7.2. In addition, a copy of the registration form will be mailed to you for your records.

Each fall, if necessary the Department may provide annual re-registration statements to all registrants. The facility should review the re-registration statement, make any necessary changes, sign and return the form within thirty (30) days. It is very important that the re-registration statement be correct, since fees are assessed based on the re-registration statements.

APPLICATION AND SHIELDING REVIEW FEES (see RHB 2.3)

Upon submission of the Facility Registration Approval Request form, each new facility must pay a non-refundable application fee of $62.50. A Facility Registration Approval will not be issued until payment of the application fee.

Each facility must also pay a non-refundable fee of $62.50 for each x-ray control upon submission of any shielding plan. A shielding plan approval will not be issued until payment of the review fee.

ANNUAL FEES (see RHB 2.10)

Any person issued or granted a registration for the possession and use of x-ray machines must pay an annual registration fee per machine tube. Annual registration fees are due on January 15 of each year. Persons failing to pay the required fees by March 15 shall also pay a penalty of fifty dollars. If the fees are not paid by April 15, the registration will be revoked, and any activities permitted under the authority of the registration must cease immediately. A registration that is revoked for failure to pay the fees may be reinstated by the Department upon payment of the required fees, the penalty of fifty dollars, and an additional penalty of one hundred dollars, if the registrant is otherwise in good standing and presents to the Department a satisfactory explanation for his failure to pay the required fees.

LEASING OF EQUIPMENT (see RHB 2.5.5)

When a facility leases x-ray equipment, it is the facility's responsibility to register the equipment and to ensure that the equipment is maintained to meet State regulations.

REPORTING CHANGES (see RHB 2.5.3)

Facilities must report to the Department, within thirty (30) days, any changes of status affecting any x-ray machine or facility. Report of a change of status must be made in writing. Changes that must be reported include:

1) Change in location or mailing address.
2) Acquiring, selling, or transferring any x-ray machine.
3) Change in facility ownership.
4) Change of the Radiation Safety Officer.
5) Changes to an approved shielding plan. This includes installation of different equipment than that which was approved, addition or deletion of components such as a vertical cassette holder, changes in use or occupancies of areas around the x-ray room, or changes in use such as adding an additional SID, or increasing the workload.

OUT OF STATE X-RAY MACHINES (see RHB 2.8)

Whenever an x-ray machine is to be brought into the State, for any temporary use, the person proposing to bring the machine into the State shall give written notice to the Department at least two working days before the machine is used in the State. If for a specific case the two working day period would impose an undue hardship on a person, he may, upon application to the Department, obtain permission to proceed sooner.

The notice shall include the type of x-ray machine, the location of the x-ray machine, the dates the machine is to be used in the State and the state the machine is registered in and the registration number.

If the x-ray machine is not registered in another state, the machine shall be registered with the Department.

If the x-ray machine is operated within the State in excess of 180 calendar days, the machine shall be registered with the Department.

In addition, the out-of-state registrant shall comply with all applicable regulations of the Department and supply the Department other information as the Department may request.

DEMONSTRATION/LOANER/TEMPORARY UNITS

As a general rule, if a demonstration or loaner x-ray unit is left at your facility for longer than 30 days, then it must be registered with the Department under your facility's name. It is the facility's responsibility to ensure that the provider of the unit is registered with the Department and to inform the Department if the unit is acquired. For demonstrations (such as c-arm fluoroscopic units or mobile radiographic units) conducted at a medical facility already possessing registered x-ray units, it is expected and required for safety precautions, such as the use of lead aprons and personnel monitoring, to be utilized. In some cases, such as for c-arm fluoroscopic units, if the unit is acquired, a shielding plan may be required depending on how and where the unit is to be used. Prior notification must be given to the Department for demonstration to be conducted at facilities not currently registered with the Department. If the decision is made to acquire the unit, it is the facility's responsibility to immediately apply for Facility Registration Approval.

For industrial demonstration units, the vendor must submit written procedures to the Department prior to conducting any x-ray unit demonstration. If the decision is made to acquire the unit, it is the facility's responsibility to notify the Department and to immediately apply for Facility Registration Approval.

For loaner units, such as temporary units in vans (CT units, cath labs, etc.) utilized during equipment replacement/room renovations, the provider of the unit must be registered with the Department, and it is the facility's responsibility to verify registration. These units are required to meet all applicable Title B regulations. The Department is required to be notified by the facility and the x-ray equipment provider prior to the use of a temporary loaner unit. The x-ray equipment provider is required to comply with all Title B requirements and supply the Department with certain information, such as the most recent performance testing results, a shielding plan, etc.

INSPECTIONS (see RHB 1.3)

After facilities and equipment are registered, the Department conducts inspections according to the following schedule:

Hospitals - Inspected every year
Mammography x-ray equipment – Inspected every year
Dental Facilities - Inspected every 4 years
All other facilities - Inspected every 2 years

Follow-up inspections are conducted as needed as a response to violations cited upon a previous inspection. The Department may also conduct Federal compliance inspections for the Food and Drug Administration within one year after new equipment is installed, regardless of the inspection schedule listed above.

QUESTIONS

If you have questions, please feel free to call or write:

SC Department of Health and Environmental Control
Bureau of Radiological Health
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
FAX (803) 545-4412

Visit our web site at: www.scdhec.net

REGULATORY GUIDES

B1 - Registration of X-ray Facilities and Equipment
B2 - Complying with Title B - Medical Facilities
B3 - Complying with Title B - Dental Facilities
B4 - Complying with Title B - Facilities Utilizing Industrial or Analytical Equipment
B5 - Vendor Registration and Responsibilities
B6 - Shielding Plans
B7 - Complying with Title B - Mammography
B8 – Complying with Title B – Bone Densitometers
B9 – Complying with Title B – Veterinary Facilities

FACILITY/EQUIPMENT REGISTRATION APPROVAL REQUEST

Facility Name:_____

Location Address:_____

_____**Phone:**_____

MailingAddress:_____**Fax:**_____

_____

Radiation Safety Officer:_____

Qualifications as RSO:_____

List doctors at the facility: (Not applicable for hospitals, academic, or industrial facilities)

_____ _____

_____ _____

Manufacturer, model #, and type of x-ray equipment to be installed:_____

_____

Expected date of installation: _____

Vendor's Name, Address, Registration #, Phone #, and Contact Person:

_____

_____

_____

Purpose for Request:

Γ New Facility

Γ Relocation of existing facility (Existing address and registration

#_____**)**

Γ Acquisition of an existing facility (Existing facility's name, address, and registration #

_____**)**

Γ Addition of equipment to an existing facility (Registration #_____**)**

Γ Replacement of equipment to an existing facility (Registration #_____**)**

ENCLOSE THE FOLLOWING ITEMS WITH THIS FORM:

1. Operating Procedures - This request cannot be processed without a copy of your operating procedures.
2. Shielding Plan, if applicable - If shielding plan has already been approved, put the log number here _____
If sending a shielding plan, include the shielding plan review fee of $62.50.
3. Operating Schedule (Mobile Facilities Only).
4. Application Fee of $62.50 (New Facilities Only).

Signature of RSO: _____
This request cannot be processed without the signature of the RSO.